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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/754,723	01/04/2001	Suad Efendic	3745.234 US	3358

7590 02/06/2002

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EXAMINER
DUFFY, PATRICIA ANN

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 02/06/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/754,723	Efendic et al
Examiner	**Group Art Unit**
DUFFY	1645

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on prelim. Amd - A 1-4-01.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 9-14 is/are pending in the application.

Of the above claim(s)____ is/are withdrawn from consideration.

☐ Claim(s)____ is/are allowed.

☒ Claim(s) 9-14 is/are rejected.

☐ Claim(s)____ is/are objected to.

☐ Claim(s)____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. § 119 (a)-(d)

☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☒ received in Application No. (Series Code/Serial Number)____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received:____.

Attachment(s)

☒ Information Disclosure Statement(s), PTO-1449, Pap r No(s). 3

☐ Interview Summary, PTO-413

☒ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other____

Office Action Summary

DETAILED ACTION

1. The amendment filed 1-4-01 has been entered into the record. Claims 9-14 are pending and under examination.

Priority

2. The status of nonprovisional parent application(s) (whether patented or abandoned) should be updated. If a parent application has become a patent, the expression "now Patent No._____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

Specification

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214

USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 9 and 10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 13 of U.S. Patent No. RE37302 . Although the conflicting claims are not identical, they are not patentably distinct from each other because the species claim of RE37302 anticipate the instantly claimed invention.

6. Claims 11-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 13 of U.S. Patent No. RE37302 in view of Campbell, I.W. In "New Antidiabetic drugs, eds C.J. Bailey and P. R. Flatt, published by Smith-Gorden 1990, pages 33-37 .

The Patent teaches the treatment of diabetic patients that are insensitive to sulfonylurea with a combination of GLP-1 amides and a sulfonylurea.

Campbell teaches that the oral hypoglycemic agents the sulphonylureas and the biguanide, metformin have been used to treat diet failed diabetic patients for over 30 years. Campbell teaches that metformin, unlike the sulphonylureas, does not cause weight gain and is therefore preferable in obese patients (page 33,

abstract). It would have been prima facie obvious to one having ordinary skill in the art to substitute metformin for the sulphonylurea in the Patent method, because Campbell teaches that metformin is preferable for treatment of obese diabetic patients.

Claim Rejections - 35 USC § 112

7. Claims 12 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claims 12 and 14, the claims are indefinite because they are improperly dependent. Claim 12 depends from a later claim and fails to further limit that claim and claim 14 is dependent on a claim that does not exist (claim 19). As such, claims 12 and 14 are indefinite.

Claim Rejections - 35 USC § 102 or 103

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

10. Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipate by Kabadi et al (Diabetes Care, 8(5):440-446, 1985.

Kabadi et al teach the treatment of type I diabetes using the combination therapy of tolazamide and insulin. Tolasamide is in a class of drugs called sulphonylurea which are oral hypoglycemic agents. Insulin is applied under the claimed provision of derivative or analogue of GLP because insulin has a single amino acid in common with GLP. As such, the combination of insulin and tolazamide administered to type I diabetics anticipates the claimed invention.

11. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buckley et al (WO 91/11457) in view of Parker et al (Diabetes, Volume 40, Suppl 1, Abstract 847).

Buckley et al teach GLP-1 peptides, 7-34, 7-35, 7-36 and 7-37 and analogs useful for the treatment of diabetes. The analogs have amino acid substitutions at positions 7-10 and/or are truncated at the C-terminus and/or contain various other amino acid substitutions in the basic peptide and include amides. These analogs provide for an enhanced capability to stimulate insulation production or exhibit increased stability in plasma as compared to GLP-1(7-37) or both (see pages 29-33, Examples 1 and 2). Buckley et al differs by not teaching the combination with oral hypoglycemic agents.

Parker et al teaches two insulin secretagogues GLP-1(7-37) and glibenclamide, an oral hypoglycemic agent, when combined had an additive effect on the amount of insulin secretion from HIT cells *in vivo*. Thus, Parker et al broadly teaches the combination of GLP-1 peptides and oral hypoglycemic agents to increase insulin secretion. Oral hypoglycemic agents are well established agents for the treatment of diabetes.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the GLP-1 peptides, 7-34, 7-35, 7-36 and 7-37 and analogs thereof as taught by Buckley et al with oral hypoglycemic agents such as glibenclamide to treat diabetes because Parker et al teach that when combined the agents had an additive effect on the amount of insulin secretion and therefore the combination would be reasonably expected to be useful in the treatment of diabetes. One would have been motivated to combine the reagents because they had an additive effect on insulin secretion.

12. Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buckley et al (WO 91/11457) and Parker et al (Diabetes, Volume 40, Suppl 1, Abstract 847) as applied to claims 9 and 10 above and further in view of Ramachandran et al (Diabete Metabolisme, 13(2):140-141, 1987).

The combination of Buckley et al and Parker et al is set forth *supra*. The combination differs by not teaching the administration of a biguanide, such as metformin.

Ramachandran et al the combination of the oral hypoglycemic agents glibenclamide and metformin is effective in the treatment of diabetes (see paragraph bridging pages 140-141).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to add the oral hypoglycemic metformin as taught by Ramachandran et al to the glibenclamide treatment method as combined *supra* because Ramachandran et al teaches that the combination of the oral hypoglycemic agents glibenclamide and metformin are effective in the treatment of diabetes and Parker et al teach that when GLP-1(7-37) and glibenclamide (ie. an oral hypoglycemic agent) are combined, the agents had an additive effect on the amount of insulin secretion and therefore the combination of all three agents would be reasonably expected to be useful in the treatment of diabetes.

13. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Habener et al (WO 90/11296) in view of Parker et al (Diabetes, Volume 40, Suppl 1, Abstract 847).

Habener et al teach amide derivatives of GLP-1 peptides useful for the treatment of diabetes (see for example pages 5-7; page 12, first full paragraph and Table 7 on page 33). These derivatives provide for an capability to stimulate insulation production for treatment of diabetes (pages 1-5). Habener et al differs by not teaching the combination with oral hypoglycemic agents.

Parker et al teaches two insulin secretagogues GLP-1(7-37) and glibenclamide, an oral hypoglycemic agent, when combined had an additive effect on the amount of insulin secretion from HIT cells *in vivo*. Thus, Parker et al broadly teaches the combination of GLP-1 peptides and oral hypoglycemic agents can increase insulin secretion. Oral hypoglycemic agents are well established agents for the treatment of diabetes.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the GLP-1 peptides, 7-34, 7-35, 7-36 and 7-37 and amide analogs thereof as taught by Habner et al with oral hypoglycemic agents such as glibenclamide to treat diabetes because Parker et al teach that when combined the agents had an additive effect on the amount of insulin secretion and therefore the combination would be reasonably expected to be useful in the treatment of diabetes. One would have been motivated to combine the reagents because they had an additive effect on insulin secretion.

14. Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Habener et al (WO 90/11296) and Parker et al (Diabetes, Volume 40, Suppl 1,

Abstract 847) as applied to claims 9 and 10 above and further in view of Ramachandran et al (Diabete Metabolisme, 13(2):140-141, 1987).

The combination of Habener et al and Parker et al is set forth *supra*. The combination differs by not teaching the administration of a biguanide, such as metformin.

Ramachandran et al the combination of the oral hypoglycemic agents glibenclamide and metformin is effective in the treatment of diabetes (see paragraph bridging pages 140-141).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to add the oral hypoglycemic metformin as taught by Ramachandran et al to the glibenclamide treatment method as combined *supra* because Ramachandran et al teaches that the combination of the oral hypoglycemic agents glibenclamide and metformin are effective in the treatment of diabetes and Parker et al teach that when GLP-1(7-37) and glibenclamide (ie. an oral hypoglycemic agent) are combined, the agents had an additive effect on the amount of insulin secretion and therefore the combination of all three agents would be reasonably expected to be useful in the treatment of diabetes.

Status of Claims

15. No claims are allowed.

16. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy, Ph.D. whose telephone number is (703) 305-7555. The examiner can normally be reached on Sunday-Thursday from 9:30 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.

Patricia A. Duffy, Ph.D.
February 4, 2002

Patricia A. Duffy

Patricia A. Duffy, Ph.D.
Primary Examiner
Group 1600